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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,447	04/27/2006	Ikurou Maruyama	2006_0649A	3430

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EXAMINER	
EPPS FORD, JANET L	
ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
08/06/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/577,447	MARUYAMA ET AL.	
	Examiner	Art Unit	
	Janet L. Epps-Ford	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5-16-2008 has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-4 are presently pending for examination.

Response to Arguments

Claim Rejections - 35 USC § 103

4. Claims 1-4 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Morgan et al. in view of NCI-Antioxidant Cancer Prevention, for the reasons of record, and further in view of Buchter-Larsen et al. (US 6,914,175), Behrend et al. (Biochemical Society Transaction, 2003, Vol. 31, part 6, pages 1441-1444), Yamaji et al., and Vieira et al.

5. Applicant's arguments filed 5-16-2008 have been fully considered but they are not persuasive. Applicants argued that: "[T]he administration of an antioxidant to a cancer patient is aimed at suppressing the side effects of an anticancer drug and it is well known that an antioxidant is not administered as an anticancer drug." Applicants

also argued that the prior art fails to disclose a cancer treatment function, or a cell killing effect which acts on a cancer cell directly. Applicants also traversed the instant rejection by way of providing a Declaration under 37 CFR 1.132 by Dr. Abeyama. Based upon this Declaration, Applicants stated that "*an antioxidant having an anticancer effect does not have a cell killing effect for cancer directly* whereas APP used in the present invention has an apoptosis induction effect for cancer cells and exhibits a cell killing effect for cancer cells directly."

Contrary to Applicant's assertions, APP and its precursor are known inhibitors of the formation of Reactive Oxygen Species, particularly they are known to inhibit the formation of hydrogen peroxide and superoxide anion. Furthermore, the prior art does support a role for antioxidants in the prevention of apoptosis, i.e. a cell killing effect. For example Yamaji et al. teaches the effects of 1,5-anhydro-D-fructose in the inhibition of LDL-oxidation (see Planta Med 2002, Vol. 68, pages 16-19). The mechanism of LDL-oxidation is known in the art to play a direct role in the promotion of apoptosis, see for example Vieira et al. (British Journal of Pharmacology, 1998, Vol. 123, pages 565-573) which describes the use of dietary antioxidants that function to inhibit apoptosis by blocking both intracellular signaling triggered by LDL oxidation and oxidized LDL-induced apoptosis. Therefore, based upon the known role that 1,5-anhydro-D-fructose has on the oxidation of LDL, and the role that oxidized LDL plays in the induction of apoptosis, the ordinary skilled artisan would expect that 1,5-anhydro-D-fructose would also function in the inhibition of apoptosis, i.e. cell killing, due to its ability to suppress LDL oxidation in a dose dependent manner, see Figure 3, page 18 of Yamaji et al.

Furthermore, in response to Applicant's assertion that APP used in the present invention has an apoptosis induction effect for cancer cells and exhibits a cell killing effect for cancer cells directly, Applicants have not presented any evidence that APP functions in a manner distinct from that which is known in the art to be associated with its precursor 1,5-anhydro-D-fructose, described above.

6. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "APP used in the present invention has an apoptosis induction effect for cancer cells and exhibits a cell killing effect for cancer cells directly") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

7. Additionally, it is clear that APP, its precursor, and compositions thereof, are known in the prior art, and are used in methods involving administration to patients. Therefore, absent evidence to the contrary, the administration of APP, its precursor, or compositions thereof would function in the same manner as recited in the intended use limitations recited in the instant claims. See, MPEP § 2112[R-3].I. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily

make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)."

Furthermore, in regards to Applicant's amendment to the claimed method to recite "whereby the growth and metastasis of such tumors is inhibited," again it is well known in the art that reactive oxygen species (ROS) are implicated in the development of cancer and metastasis (see Behrend et al. 1st paragraph, page 1441). Moreover, Behrend et al. states that: "[T]he response to mitogenic as well as to cytokine signals can be diminished by non-enzymic and enzymic *antioxidants,* which implies a direct role for ROS as second messenger molecules in transducing receptor initiated signaling cascades that control diverse cellular events such as proliferation, apoptosis and inflammation." (page 1441, last ¶) Furthermore, Behrend et al. teaches that there is a growing body of evidence that suggests that elevated levels of ROS form a part of signaling cascades that induce and maintain the oncogenic phenotype of cancer cells, and the finding that *elimination of excessive ROS by chemical or enzymatic antioxidants decreases tumorigenicity* of various types of tumor cells has opened upon new areas for research in cancer biology (see last paragraph of page 1442).

Therefore, contrary to Applicant's assertions, the prior art clearly suggests the use of antioxidants, for the elimination of excessive ROS, therefore leading to the reduction of tumorigenicity of various type of tumor cells, including metastatic growth of tumors as taught by Behrend et al. Moreover, the prior art also provides a clear suggestion for the use of the antioxidants of the instant invention as a potent scavenger of reactive oxygen species. Therefore, the ordinary skilled artisan would have been

motivated to use the prior art antioxidants recited in the instant claims in a method for inhibiting both the growth and the metastasis of tumors.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Ford/
Primary Examiner, Art Unit 1633

/J. L. E./
Primary Examiner, Art Unit 1633